

**REMARKS**

Applicants express their appreciation for the indication that the election of species requirement has been withdrawn. Claims 34 and 35 have been amended to recite that the seed, seed parts, and progeny are "transgenic", support for which is contained throughout the specification. No new matter has been added. Entry of the amendments is respectively requested.

**35 U.S.C. § 101 - NON-STATUTORY SUBJECT MATTER**

Claims 34 and 35 have been rejected as directed to non-statutory subject matter under 35 U.S.C. § 101. These claims have been amended to further define the seed, seed parts and progeny as "transgenic," thus distinguishing these products from products of nature. Thus, Applicants respectfully request withdrawal of the rejections.

**35 U.S.C. § 112- ENABLEMENT**

Claims 1-24 and 33-35 have been rejected as non-enabled on numerous grounds. Applicants respectfully traverse each and every ground of objection, and submit that the claims are enabled by the specification.

On page 7, Examples I-V have been criticized as including only "very rudimentary" experimental details and closes with statements to the effect that the transformation was done, crosses were done, and progeny were selected, without details of what, if any, of the examples produced any of the desired progeny, having the desired heterologous nucleic acid transferred from the first plant to the second plant. On the top of page 8, it is further alleged that no information is given on any of the putative *Spm* transformants and related heterologous nucleic acid transferred, and that there are no examples of any recombinase, wherein the excisable flanking sequence comprise a recombination site and the first and second plant produce the compatible recombinase. The conclusion is

that the claimed invention is not exemplified. Applicants respectfully disagree.

Contrary to the allegations in the Office Action, Example I (on pages 16-17) illustrates introduction of nucleic acid from transformed *Orychophragmus* to *Sinapis alba* and various species of *Brassica* via crossing, and the production of F1 and F2 progeny (of the resultant unstable hybrids producing via the crossing) containing the nucleic acid. Specifically, *Agrobacterium*-based constructs carrying *Spm* transposase and non-autonomous *dSpm* elements (of which three examples are given), inserted between the 35S CaMV promoter and GUS gene, were used to transform *Orychophragmus*, followed by crossing. The resultant hybrids were then selected for the presence of *dSpm* element. As disclosed on pages 16-17, "The resultant hybrids were allowed to self and the F<sub>1</sub> progeny has been selected for the presence of *dSpm* element (PCR analysis or phosphinotricin resistance). Those surviving selection were further screened for pure *Brassica* phenotype and absence of GUS activity."

Thus, the claimed invention is in fact, exemplified, and in a reproducible manner. The lack of exemplification in examples I-V of the use of a recombinase is not fatal. It is well settled that Applicants do not have to exemplify, or for that matter disclose each and every embodiment embraced by their claims, even in an unpredictable art. See, *In re Angstadt*, 190 U.S.P.Q. 214, 218 (CCPA 1976). As the Court of Customs and Patent Appeals has recognized:

The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

*In re Marzocchi*, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Besides, one skilled in the art would appreciate that once the recombination site is transferred into the genome of the

recipient (via the transposase and transposable element as illustrated in example 1), a recombinase may then be used to introduce exogenous DNA of interest to that specific site.

On pages 8-9, the Office action states that undue experimentation would be required to select first and second plants that are not members of the same genus or species, based on the allegation that Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually *ad infinitum* of possibilities, other than by random trial and error, which is excessive experimentation and an undue burden.

Here again, contrary to the allegations in the Office action, Example I describes using *Agrobacterium*-based constructs and crossing *Orychophragmus violaceous* with either a *Brassica* species or *Sinapsis alba* to produce "resultant hybrids." Plainly, the plants illustrated in these examples are not members of the same genus or species. In addition, the specification (page 14, lines 24-26) provides additional examples of plant combinations including *Arabidopsis*/cotton, *Arabidopsis*/soybean, *Arabidopsis*/rice and tobacco/soybean, as well as *Arabidopsis thaliana* or *Brassica napus* with potato, maize or wheat (examples II-V on pages 17-18). Further, Applicants submit that one skilled in the art would be able to utilize standard techniques known in the art at the time the claimed invention was made, to select pairs of plants that upon crossing, produce unstable progeny or demonstrate preferential segregation or sorting out. Enablement is not precluded by the necessity for some experimentation such as routine screening even if that screening involves hundreds of samples. *In re Wands*, 858 F.2d 731, 740, 8 U.S.P.Q.2d 1400, 1407 (Fed. Cir. 1988). Thus, what is important in evaluating enablement is the nature of the experimentation, and not the quantity of experiments performed. *Id.* Persons skilled in the art would be

able to select between pairs of plants that would be operable in the claimed invention and those that would not work.

On pages 9-11, the Office Action addresses recombinases, which are the subject of only claim 3. The allegations are that Applicant gives no information or guidance with respect to the use of the specific recombination system, including proper conditions such as time, place, concentration, phase of the cell cycle, and duration of time for the desired recombination event to occur, and that absence such guidance, and in view of the complexity of recombinase systems, undue experimentation would be required in order to make the selections, and to eliminate inoperable embodiments. Applicants traverse this ground of rejection as well.

Contrary to allegations in the Office action, the specification provides adequate teachings with respect to the recombinase systems that may be useful in the claimed invention:

The heterologous DNA is integrated in a specific site of the recipient genome by use of a recombinase and recombination site combination. Site-specific recombinases from bacteriophage and yeasts are being widely used as tools for manipulating DNA both in the test-tube and in living organisms. Preferred recombinases/recombination site combinations for use in the present invention are *Cre-Lox*, *FLP-FRT*, and *R-RS*, where *Cre*, *FLP* and *R* are recombinases, and *Lox*, *FRT*, and *RS* are the recombination sites.

Specification p. 10, lns. 20-24). The specification also teaches that "To be functional in plants, these sites require 7-8 base pairs (bp) of core sequence between 12-13 bp inverted repeats." (Specification p. 10, lns. 25-27). In addition, on page 11, lines 10-12, the specification references several publications that teach how to use suitable recombination systems in living cells, including Sauer, U.S. Patent 4,959,317 (yeast), Odell *et al.*, U.S. Patent 5,658,772 (plants), and Hodges and Lyznik, U.S. Patent 5,527,695 (eucaryotes in

general). In view of these teachings, Applicants submit that persons skilled in the art would be able to select recombinases/recombination sites for use in the claimed invention without undue experimentation. Notwithstanding the Examiner's concerns, limitations with respect to the "proper time, place, concentration, phase of cell cycle, and duration of time to use the recombinase" are not critical to the practice of the claimed invention. Thus, one skilled in the art would be able to select them and select, adjust or optimize those parameters as desired, without undue experimentation.

In view of the foregoing, reconsideration and withdrawal of the rejection are respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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